The Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019 establishes a streamlined administrative process which allows the FDA to modify a drug's safety labeling to address new health risks. The act is intended to modernize and accelerate regulatory procedures applicable to OTC drugs and will also allow for increased innovation. However, patient safety and manufacturer accountability are of equal importance. As such, nothing in this act is intended to change, diminish, or prohibit a manufacturer from performing any duty or complying with any requirement to warn consumers that exists under State or Federal law or to prevent any labeling changes pursuant to any other applicable provision of the Federal Food, Drug, and Cosmetic Act or FDA regulation. It is imperative that consumers have accurate information regarding the safety of over-the-counter drugs, and this bill is intended to improve that process while maintaining the existing rights of consumers to access the courts and hold manufacturers accountable when harmed.

This legislation has bipartisan support and also broad support from key stakeholders in public health, healthcare, and industry. I am deeply grateful for the work of my colleagues, notably Senator JOHNNY ISAKSON—the bill's sponsor; and the chairman and ranking Member of the Committee on Health, Education, Labor, and Pensions, Senator LAMAR ALEXANDER and Senator PATTY MURRAY, and their staffs for their continued support for this important effort. As a result of our work, American consumers will be able to have greater confidence in their over-the-counter drugs and will benefit from new innovation in the years to come.

Mrs. MURRAY. Mr. President, I thank Senator CASEY for his leadership on this important issue and agree wholeheartedly with his statement on S. 2740, the Over-the-Counter Monograph Safety, Innovation, and Reform Act of 2019.

Mr. BURR. Madam President, I want to take a few moments to explain why I am opposed to the OTC reform legislation offered by Senator ISAKSON. Senator ISAKSON and I worked together on many pieces of FDA legislation, and I have no doubt that he worked tirelessly to draft this bill in the best interest of patients. I will miss working closely with my colleague from Georgia to improve the lives of the millions of Americans touched by the U.S. Food and Drug Administration's work each day.

I want to be clear that I agree reforms are needed within the over-the-counter drug division at the FDA. I simply disagree on the way in which this legislation provides the resources to achieve these reforms because I do not believe it will result in my colleague's desired outcome. Here is why.

I reformed the FDA in 1997 with the passage of the FDA Modernization Act, which I like to call FDAMA. One of the foundational principles of that legislation was to bring more certainty, predictability, and accountability to an agency that had lost its way, failing to bring new drugs and medical devices to market in the United States in a timely manner. Twenty-two years later, I am starting to see the implementation of major provisions of this law. Two decades after its passage, the FDA is finally putting key policies into practice that Congress demanded. Two decades is an unacceptable amount of time for Americans to wait.

One of the components of FDAMA was the reauthorization of certain user fee programs. Over these past two decades, we have seen FDA's user fee agreements increase with each 5-year cycle, bringing more resources into the agency to review drug, biologic and device applications.

When the drug industry first agreed to user fees in 1993, the fee to file a new drug application with the FDA was $100,000. Today, that fee is $2.1 million. To that end, FDA has struggled to uphold its end of the deal, falling behind in its commitment to hire the number of individuals the agency needs to actually review the applications that cost millions of dollars to file. The FDA continues to increase the amount of user fee dollars it requires to review applications, eroding the balance of congressional oversight provided by the appropriation of taxpayer dollars to the agency.

I would caution my colleagues that we are currently experiencing the effects of a center at the FDA that receives 100 percent of its funds from user fees, the Center for Tobacco Products. The CTP has had 10 years and received over $5 billion in user fee resources. It has yet to finalize a single governing regulation for the products Congress tasked the CTP with regulating. Meanwhile, youth rates of vapor product use continue to increase and 2,000 Americans have fallen ill from the use of unregulated products. I have spoken many times on my concerns with the growth and development of FDA user fee programs because they have not resulted in the development of an FDA that keeps its promises. I promise my colleagues that the user fee program included in this bill will not be any different.

While the Senate has wrestled with solutions to high drug costs for the last 18 months, we are voting to approve a bill that increases the development costs for one of Americans' cheapest options for care. The over-the-counter user fee bill provides millions of dollars in new industry funds to reform the OTC system at FDA, and the agency is asking for tens of millions of dollars to deal with a backlog of OTC monographs or recipes to create over the counter medications.

User fee dollars are intended to go toward the review of applications, but I can assure my colleagues this is not the full story at the Agency today. Last year alone, $133 million in drug user fees went toward administrative expenses at the FDA, funds that may otherwise help to invest in new treatments or cures for Americans. This is very simple math, the more user fee programs we provide to the FDA, the less the FDA is accountable and responsive to Congress.

Through FDAMA and more recently in the 21st Century Cures Act and the 2017 FDA user fee bill, I worked to rebalance the focus of the FDA, to reaffirm its authorities to regulate the cutting edge science facing the agency, and to better leverage and strategically invest its existing resources. So I cannot support legislation that degrades the progress we have made at the FDA.

REMEMBERING RACHELLE BERGERON HAMMERLING

Mr. RUBIO. Madam President, today, I honor the life and work of Rachelle Bergeron Hammerling, a human rights lawyer who served as the acting Attorney General of Yap in Micronesia when she was murdered just a couple of months ago. Rachelle was killed in front of her home on October 14, 2019, as a direct result of her courageous fight against human trafficking, domestic violence, and sexual abuse. She was just 33 years old, but her legacy will live on through her family and the communities she made the ultimate sacrifice to serve.

Rachelle was born in Waukesha, WI, to parents Thomas and Tammy Bergeron in 1986. After growing up in Wisconsin, Rachelle went on to obtain a juris doctorate from the University of Florida College of Law in 2010, an experience her family says she loved.

When Rachelle graduated from law school, her passion to help others led her to volunteer with the International Justice Mission in India, where she represented women and children who had been trafficked. Rachelle spent her career prosecuting criminals involved with sex trafficking and worked tirelessly to protect the poor against violence. Rachelle's work took her around the United States, including New York and Washington, DC. She was a member of the New York State Bar and created the ''Not-So-Super'' campaign video as an effort to raise awareness regarding human trafficking during the 2014 Super Bowl. Her work took her to Beijing, South Africa, India, and finally the Pacific island of Yap.

Rachelle fought to give a voice to the voiceless and dedicated her life to empowering and uplifting others. About 4 years ago, Rachelle moved to Yap after accepting a job as that community's assistant attorney general. Since January 2019, she had been serving as the island's only prosecutor and as the acting attorney general, where her duties included being a part of a human trafficking task force. Rachelle was very active in the community she served and spent a lot of time in local schools

and community centers to warn against the dangers of sex trafficking.

Rachelle also met her husband, Simon Hammerling during her time in Yap. The two were married in 2018 and had planned to take in a young girl they had found sleeping on their doorstep. Rachelle passed just before the two were about to celebrate their 1-year wedding anniversary and shortly before she and her family were due to move back to the United States for a new job in Wyoming. Her passing is a tremendous loss to her family, to the community she fought to serve, and to all who knew her.

We remember Rachelle with gratitude for her life, and we honor her for her sacrifice. Scripture tells us that the righteous will rest from their labor, for their deeds will follow them. As she now rests from her tireless and courageous work on behalf of the most vulnerable among us, we know Rachelle's deeds will follow her and continue to inspire others to pursue justice as fiercely as she did.

TRIBUTE TO CAROLYN EDWARDS

Mr. BARRASSO. Madam President, together with Senator CARPER, I rise today to recognize Carolyn Edwards for her distinguished career and significant accomplishments at the Federal Highway Administration, FHWA.

After 46 years of exceptional Federal service, Carolyn is retiring from FHWA on January 3, 2020. She is a dedicated public servant recognized as an unparalleled national expert on Federal Highway Programs and the highway trust fund. Through her technical assistance to Congress and her policy advice to departmental and agency officials, Carolyn has provided an invaluable contribution to the programs that support our Nation's roads and bridges. She has helped to shape not only these critical highway programs, but also, as colleague and mentor, she has shaped and guided a generation of highway policy experts. Her work will have a lasting legacy for many years to come.

Carolyn's entire 46-year Federal career has been with the U.S. Department of Transportation, USDOT—44 of these with FHWA. To put Carolyn's remarkable public service longevity in perspective, FHWA was formed in 1966, only 7 years prior to her arrival. She joined FHWA in 1973 as an economist. Over the ensuing four and a half decades, she has served in a range of high-level analytical and leadership positions, including positions in FHWA's Office of Highway Policy Information and Office of Legislative Affairs and Policy Communications. She also worked in the Office of the Secretary's Office of the Assistant Secretary for Budget and Programs with a portfolio that covered FHWA programs.

Carolyn is currently a member of FHWA's Legislative Analysis Team, where she serves as the authoritative expert on a wide range of highway-related topics, including Federal highway legislation, the highway trust fund, and the operations of the Federal-aid highway program. Throughout her successful and impressive career, she has been a ''go-to reference'' on these topics for both agency and departmental leaders and staff.

Among her many exemplary accomplishments, Carolyn has been in the development and implementation of every Federal surface transportation bill since the Transportation Equity Act for the 21st Century—TEA–21—was enacted in 1998. Additionally, she has also been a recipient of several prestigious honors and awards. Carolyn has been recognized with a Secretary's Team Award, two Secretarial Awards for Partnering for Excellence, and multiple FHWA Superior Achievement Awards, FHWA's highest honor award.

Carolyn exemplifies the highest standards of public service and embodies FHWA's spirit of professionalism and customer service. Over the years, the Senate Committee on Environment and Public Works, along with other congressional committees, Members of Congress, and their staff have relied on Carolyn's legislative and highway policy expertise, quick turnaround technical assistance responses, and wealth of information. Carolyn's colleagues at USDOT and FHWA have depended on her tireless efforts, her endless wealth of knowledge and willingness to share and transfer it. They will miss her indomitable spirit and her purple sweaters, purple pens, and love for everything purple to brighten their days.

Carolyn has helped shape highway policy discussions and implement new programs. Her contributions will continue to make a difference on USDOT, FHWA, and the surface transportation community. Her retirement from the Federal Government is a celebration of her dedication to the American people.

It is a great honor to recognize this exceptional public servant. Senator CARPER joins me in extending our appreciation and well wishes to Carolyn on her retirement.

ADDITONAL STATEMENTS

TRIBUTE TO ANDY PRADELLA

● Mr. MANCHIN. Madam President, Gayle and I would like to extend our warmest congratulations and very best wishes to our very dear friend Andy Pradella on his 70th birthday. What I have always admired about Andy is his unparalleled work ethic and determination to learn and serve, and to inspire those around him. I can't tell him how much his and Joanie's friendship has meant to me and Gayle throughout the years. They are like family to us. Together, they are both a match made in ''Almost Heaven.''

While Andy wasn't born in West Virginia, he certainly is a West Virginian in his heart and soul. In West Virginia, if you are hungry, you will be fed. If you are lost, someone will not only give you directions but will offer to drive you to your destination. I am so deeply proud of the people of my home State and the values that make us stand out from the rest of the Nation.

It is in that same spirit that I proudly recognize Andy Pradella as an honorary West Virginian. No one fits this title better. He is one of the most generous, kindest, selfless people I have had the privilege of calling my very dear friend. He has provided so much happiness and wisdom to the lives of those around him throughout the years, and it is my wish that the memory of this special day remains with him just as his guidance and influence will remain in all the lives he has touched. Again, it is with the greatest admiration that I send to him my best wishes on his special day.

Andy, please always remember that no matter where you are, you have a home here in ''Almost Heaven.''●

TRIBUTE TO MARY HULSMAN ALLGEIER

● Mr. PAUL. Madam President, Mary Hulsman Allgeier was selected as the #1 Citizen of Schnitzelburg, a historic neighborhood in Louisville, KY. Mary has been a lifelong community advocate and volunteer. She has given to and supported those in need as a leader in Holy Family Parish for many years. In addition, Mary is a role model for women in leadership and is instrumental in ensuring members of her community understand their civic rights and responsibilities. Mary has served her community faithfully from education to civic engagement and is an example for us to follow. I am proud to join the people of Schnitzelburg in honoring Mary Allegeier as their #1 Citizen.●

TRIBUTE TO COLONEL FRED JOHNSON

● Mr. PAUL. Madam President, Col. Fred Johnson, U.S. Army, Retired, was honored as Kentucky's 2019 Veteran of the Year. Since his retirement from the U.S. Army in 2014, Fred Johnson has immersed himself in community service in Louisville in both existing programs, such as YouthBuild and Restorative Justice Louisville, and through developing new, innovative ways to use the arts and storytelling to help connect veterans with the broader community. His Veteran's Writing Workshop series and the innovative Shakespeare with Veterans group that he cofounded in 2016 are helping veterans communicate their stories in creative and timeless ways. Colonel Johnson remains committed to our country as is evident by his decision to teach sixth grade Social studies class at Thomas Jefferson Middle School. I am proud to recognize Col. Fred Johnson as a remarkable symbol of the rich veteran heritage of Kentucky.●